FDA Hearing on OTC Drugs
June 28, 2000

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CTFA

- 106 Year Old Trade Association
- Represent 600 Companies
  - 300 Manufacture or Distribute Personal Care Products (Cosmetics and Drugs)
  - 300 Supply Goods and Services
- Many CTFA Members Manufacture or Distribute Products that Are Regulated as Both Cosmetics and Drugs

Rx – OTC – Cosmetic-Drugs

- Broad Spectrum of Products
  - Heart Drugs to Antiperspirants
- Rx to OTC Switches Allow Flexibility
  - Consumer Availability and Choice Where Safety Permits
- Greater Flexibility Should Be Allowed for OTC Monograph Drugs

What are Cosmetic-Drugs?

- Sunscreens
- Antiperspirants
- Antidandruff Shampoos
- Antimicrobial Soaps and Washes
- Skin Protectants
- Acne Remedies
- Oral Care Products

Why Are They Different?

- Different Marketing Channels
- In many cases they are purchased for their cosmetic attribute, but also provide important drug benefits
- Broad consumer availability provides a public health benefit

  Small packages (convenience sizes) are essential for consumers to realize the benefit from these products.

The OTC Drug Review

- Issues
  - OTC Drugs = Wide Variety of Products
  - 1972 to 2000 and beyond
  - FDA Must Understand the Marketplace for the Products it Regulates
  - International Harmonization
  - Flexibility

OTC Monograph Flexibility

What is the Problem?

- Process is too slow
- Failure to Distinguish Between NDAs and Monograph Process
  - Monograph Process Should be More Open
  - Need for More Flexibility and Consumer Choice
- Need to Recognize New Ingredients
- Need to Recognize New Product Forms

OTC Monograph Flexibility

- What is the Problem?
  - Failure to Rapidly Update Agency Knowledge
    - Science
    - Formulation Technology
    - Testing Methods

OTC Monograph Flexibility

- What is the Problem?
  - International Harmonization
    - Material Time and Extent Barriers
    - Labeling Harmonization Where Possible
    - Cosmetics in Europe – Drugs in the U.S.

OTC Monograph Flexibility

- What is Necessary?
  - Increased resources and focus on monograph issues (No change in the law is necessary)
  - FDA policy encouraging more frequent communication with interested parties throughout the rulemaking process
  - Faster review and approval of new active ingredients (domestic and foreign)

OTC Monograph Flexibility

- What is Necessary?
  - More FDA outreach to understand how the marketplace and products are evolving
  - Cooperation with Foreign Governments and the International Industry (CHIC Process for CFSAN and CDER is positive step)
  - Flexibility for Cosmetic-Drugs
    - Broad Availability of Cosmetic-Drugs for Consumers in Convenient, Attractive to Use Formulas
    - If it isn't used, it can't be effective

Two Case Studies

- 1. OTC Drug Labeling Regulation
- 2. Sunscreen Monograph

Case Study – OTC Labeling

- Rulemaking applied to all OTC Drugs
- Rigid format requirements for labeling
- Sound concept – flawed execution
- Barrier to International Harmonization
- Failure to recognize the broad range of products that constitute OTC drugs
  - Cough and cold to antiperspirants
  - Small packages for consumer convenience
  - Consumer needs sacrificed for "one size fits all" philosophy

Case Study - Sunscreens

- Sunscreens Provide Important Public Health Benefits
- Sunscreens prevent disease
  - Skin Cancer
- Disease Prevention Should Have High Priority
- Manufacturers Should Be Permitted to Communicate About Product Benefits with Doctors and Patients through Labeling

Case Study - Sunscreens

- The World at the Start of the OTC Review
  - Traditional Sunscreens for Beach Use
  - No System for Measuring Protection
  - Less Knowledge Linking Sun Exposure to Skin Cancer
  - Role of UVA Not Fully Understood
  - Fewer Active Ingredients

Case Study - Sunscreens

- The World in 2000
  - Beach/Outdoor Products
  - Sport Products
  - Skin Care and Foundation Products
  - Lipsticks
  - Improved formulation technology for all products to make them more attractive for consumer use

Case Study - Sunscreens

- The World in 2000
  - Better Understanding of Health Benefits
    - Sunburn Protection
    - Skin Cancer
    - Anti-aging
  - Better Protection – Better Measurements
    - High SPF Products
    - UVA Protection

Case Study - Sunscreens

FDA Should Encourage Sunscreen Products that Further Public Health and Prevent Disease

- Encourage Innovation
- Encourage Broad Availability as Traditional Drugs and Cosmetic-Drugs
  - The cosmetic industry has provided major benefit to the consumer by making sunscreen protection available in a wide range of cosmetic products

Case Study - Sunscreens

- FDA Should Not Be A Barrier to Innovation and Communication
  - Truthful Labeling Should Be Allowed
    - High-SPF Products
    - Anti-aging benefits
  - Manufacturers Should Be Given Some Flexibility in How They Communicate with the Consumer.
  - Consumers are better informed and want information.

Conclusion

- Self-Medication is a Critical Part of our Healthcare System
- FDA Should Be At the Leading Edge of Knowledge about OTC Drug Products
- FDA Needs Adequate Resources and Focus for OTC Drugs
- FDA Should Work Quickly to Resolve Safety and Efficacy Issues
- FDA Should Let the OTC Drug Marketplace Work Efficiently with Minimal Interference